ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[OPTS-50575; FRL-3658-5]
RIN 2070-AB27

Significant New Uses of Certain Chemical Substances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is promulgating significant new use rules (SNUR) under section 5(a)(2) of the Toxic Substances Control Act (TSCA) for several chemical substances which were the subject of premanufacture notices (PMNs), and are now subject to TSCA section 5(e) consent orders issued by EPA. Today's action requires certain persons who intend to manufacture, import, or process these substances for a significant new use to notify EPA at least 90 days before commencing the manufacturing or processing activity designated by this SNUR as a significant new use. The required notice will provide EPA with the opportunity to evaluate the intended use, and, if necessary, to prohibit or limit that activity before it occurs. EPA is promulgating these SNURs using direct final procedures.

EFFECTIVE DATE: The effective date of this rule is June 25, 1990.

Comment. If EPA receives notice before May 24, 1990 that someone wishes to submit adverse or critical comments on EPA's action in establishing a SNUR for one or more of the chemical substances subject to this rule, EPA will withdraw the SNUR for each substance for which the notice of intent to comment is received, and will issue a proposed SNUR providing a 30-day period for public comment.

ADDRESSES: Each comment or notice of intent to submit adverse or critical comments must bear the docket control number [OPTS-50575] and the specific CFR section number for the substance being addressed. Since some comments may contain confidential business information (CBI), all comments should be sent in triplicate to: TSCA Document Receipt Office (TS-790), Office of Toxic Substances, Environmental Protection Agency, Rm. E-105, 401 M St., SW., Washington, DC 20460, Attn: Significant New Use Rules.

Nonconfidential versions of comments on this rule will be placed in the rulemaking record and will be available for public inspection. Unit X of this preamble contains additional information on submitting comments containing CBI.

FOR FURTHER INFORMATION CONTACT: Michael M. Stahl, Director, Environmental Assistance Division (TS-799), Office of Toxic Substances, Environmental Protection Agency, Rm. E-543B, 401 M St., SW., Washington, DC 20460, Telephone: (202) 554-1404, TDD: (202) 554-0551.

SUPPLEMENTARY INFORMATION: This rule describes significant new uses and recordkeeping requirements for certain persons who intend to manufacture, import, or process certain chemical substances designated in the rule. Each of the following substances designated in today's rule was the subject of a PMN and a TSCA section 5(e) consent order issued by EPA. The substances are identified by generic chemical names because the specific names have been claimed as CBI (see Unit VII).

PMN Number	Chemical Name
P-89-448	(generic) Alkanepolyol phosphate ester
P-89-650	(generic) Substituted ethylene diamine, methyl sulfate quaternized
P-89-653	(generic) Adipic acid, polymer with 1,4-cyclohexanedimethanol, dipropylene glycol, alkanepolyol, substituted alkanolamines, and carbomonocyclic dicarboxylic acid
P-89-703, P-89-755, and P-89-756	(generic) Reaction products of secondary alkyl amines with a substituted benzenesulfonic acid and sulfuric acid

This is the first rule EPA has issued using the expedited procedures and standard significant new use designations established in EPA's recent amendments to 40 CFR part 721. (See 54 FR 31308, July 27, 1989.) The preamble to this rule explains in detail the background and rationale supporting the use of the new expedited process. Where appropriate, future rules issued using the expedited process will contain an abbreviated version of this background information but will cross-reference the more complete explanation in the preamble of this rule.

I. Authority

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a "significant new use." EPA must make this determination by rule after considering all relevant factors, including those listed in section 5(a)(2). Once EPA determines that a use of a chemical substance is a significant new use, section 5(a)(1)(B) of TSCA requires persons to submit a notice to EPA at least 90 days before they manufacture, import, or process the substance for that use. The mechanism for reporting under this requirement is established under 40 CFR 720.10.

II. Objectives and Rationale for Expedited SNUR Process

A. PMN Review and Use of Section 5(e) Orders

A limited amount of toxicity data is typically submitted with PMNs. Thus EPA bases its review of new substances primarily on structure-activity relationships (SAR). During PMN review, EPA may determine that "the information available* * *is insufficient to permit a reasoned evaluation of the health and environmental effects" of the new chemical substance that is the subject of the PMN. At the same time, EPA may determine, under section 5(e)(1)(A)(ii)(I), based on SAR analysis that activities involving the new substance "may present an unreasonable risk of injury to health or the environment." When EPA makes these two findings, it acts under section 5(e) to regulate the activities involving the new substance which contribute to the potential risk.

In most such circumstances, EPA believes that it is appropriate to negotiate an order (known as a "consent order") under section 5(e) with the PMN submitter to control human exposure and/or environmental releases until test data or other information sufficient to assess adequately the potential hazard become available. Section 5(e) consent orders have specified a variety of control measures, including protective equipment, use limitations, process restrictions, labeling requirements, and limits on environmental release. Some recent consent orders have included testing requirements that are triggered when specified levels of production volume or other indices of increased exposure are reached; under these orders, the submitter may not exceed the production volume limitation or other restriction imposed by EPA until test data specified by EPA have been submitted to and reviewed by EPA.

In other instances, during PMN review EPA may determine under section 5(e)(1)(A)(ii)(II) that a new substance will be produced in substantial quantities and "may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance," and that the available information is insufficient to determine the effects of the substance.

Consent orders issued to address concerns under section 5(e)(1)(A)(ii)(II) may include recordkeeping provisions and production volume limits.

B. Use of SNURS as a Follow-Up Tool for Substances Subject to Section 5(e) Consent Orders

Section 5(e) orders apply only to PMN submitters. When a PMN submitter commences commercial manufacture of the substance and submits a Notice of Commencement of Manufacture to EPA, EPA adds the substance to the TSCA Chemical Substance Inventory maintained pursuant to section 8(b) of TSCA. When a substance is listed on the Inventory, it is no longer a "new chemical substance" for which a PMN would be required under section 5(a)(1)(A). Thus, under section 5(e) alone other persons would be able to manufacture, import, or process the substance without EPA review and without the restrictions imposed on the PMN submitter by the section 5(e) order.

EPA uses its SNUR authority to extend limitations in section 5(e) orders to other manufacturers, importers, and processors. This ensures that the original PMN submitters and subsequent manufacturers, importers, and processors are treated in an essentially equivalent manner. These SNURs are framed so that non-compliance with the control measures or other restrictions in the section 5(e) consent orders is defined as a "significant new use." Thus, other manufacturers, importers, and processors of the substances must either observe the SNUR restrictions or submit a significant new use notice to EPA at least 90 days before initiating activities that deviate from these restrictions. After receiving and reviewing such a notice, EPA has the option of either permitting the new use or acting under section 5(e) or (f) to regulate the new submitter's activities.

In addition to assuring that all manufacturers, importers, and processors are subject to similar reporting requirements and restrictions, SNURs for these substances have the following objectives: That EPA will receive notice of any company's intent to manufacture, import, or process a chemical substance listed on the TSCA Inventory for a significant new use before that activity begins; that EPA will have an opportunity to review and evaluate data submitted in a SNUR notice before the notice submitter begins manufacturing, importing, or processing a listed chemical substance for a significant new use; and that, when necessary to prevent unreasonable risks, EPA will be able to regulate prospective manufacturers, importers, or processors of a listed chemical substance before a significant new use of that substance occurs.

C. Substances That May Raise Concerns But Are Not Regulated Under Section 5(e) –

EPA also reviews some new substances that do not warrant action under section 5(e) but merit other follow-up monitoring and evaluation. On the basis of test data or structure-activity relationships analysis, EPA may identify potential health or environmental effects that could create a basis for concern if, because of changes in use and related activities, the substance's exposure or release potential later changes or increases beyond that described in the PMN.

In most such cases, EPA believes it is appropriate to use SNUR authority to monitor the commercial development of these substances so that EPA can be apprised of significant increases in exposure potential, which may warrant control measures or testing.

D. Rationale for Significant New Use Designations

To determine what constitutes significant new uses, EPA considers relevant information about the toxicity of the substance, likely exposures associated with possible uses, and the four factors listed in section 5(a)(2) of TSCA. EPA designates the significant new uses of each substance based on these considerations.

In cases where significant new use designations are based on provisions in the section 5(e) order, EPA has already made a determination either under section 5(e)(1)(A)(ii)(I) (i.e., that activities involving the substance may present an unreasonable risk of injury to health or the environment), or under section 5(e)(1)(A)(ii)(II) (i.e., that the substance may be produced in substantial quantities and may enter the environment in substantial quantities or there may be significant or substantial human exposure). While such a finding is not necessary to promulgate a SNUR, it strongly supports a determination that the uses of the substance designated in the rule would be significant new uses of the substance. In this and future SNURs, for each substance subject to a section 5(e) order, EPA will specify the findings that served as the basis of the order.

For substances not subject to a section 5(e) order or when EPA believes that SNUR requirements should include provisions which did not appear in a section 5(e) order, the additional provisions will conform to the criteria in 40 CFR 721.170, and the basis for these additional provisions will be explained.

E. Conversion of Section 5(e) Orders Into SNURS

The standard significant new use designations in subparts B and C of 40 CFR part 721 are designed to be consistent with standard provisions for section 5(e) consent orders. Because section 5(e) orders are framed to apply only to PMN submitters, however, minor wording changes may be needed to convert the orders' provisions into generally applicable requirements. Under § 721.160(b), EPA may make such wording changes provided that they do not depart from the section 5(e) order's substantive requirements. All of the SNURs in today's rule are based on recently issued section 5(e) orders, and only minor wording changes are necessary to convert the requirements into SNURs.

Some earlier section 5(e) orders contain provisions that require major wording changes to be converted into SNURs. Where a particular requirement in a section 5(e) order is worded so differently from the corresponding SNUR provision that the basis for selecting the SNUR provision would not otherwise be evident, EPA will provide an explanation for its choice of SNUR provisions.

III. Applicability of General Provisions

General provisions for SNURs appear under subpart A of 40 CFR part 721. These provisions describe persons subject to the rule, recordkeeping requirements, exemptions to reporting requirements, and conditions of advance compliance for uses occurring before the effective date of the final rule. See 53 FR 28358 (July 27, 1988).

EPA has recently amended 40 CFR part 721 by establishing new subparts B, C, and D. See 54 FR 31306 (July 27, 1989). Subpart B establishes standard significant new use designations. Subpart C establishes recordkeeping requirements. Each standard significant new use and recordkeeping requirement will apply to a specific substance only if it is cited in the SNUR for that substance. Subpart D contains expedited procedures for establishing significant new use requirements for certain new substances that are regulated under a section 5(e) consent order. Subpart D also contains criteria to determine whether uses not identified in the PMN of non-section 5(e) substances will be considered candidates for a SNUR under expedited procedures. SNURS for specific substances are contained in subpart E.

Rules on user fees appear at 40 CFR part 700.

Persons subject to this SNUR must comply with the same notice requirements and EPA regulatory procedures as submitters of PMNs under section 5(a)(1)(A) of TSCA. In particular, these requirements include the information submission requirements of section 5(b) and (d)(1), the exemptions authorized by section 5(h)(1), (2), (3), and (5), and the rules in 40 CFR part 720. Once EPA receives a SNUR notice, EPA may take regulatory action under section 5(e), 5(f), 6, or 7 to control the activities on which it has received the SNUR notice. If EPA does not take action, EPA is required under section 5(g) to explain in the **Federal Register** its reasons for not taking action.

Persons who intend to export a substance identified in a proposed or final SNUR are subject to the export notification provisions of TSCA section 12(b). The rules that interpret section 12(b) appear at 40 CFR part 707. Persons who intend to import a chemical substance identified in a final SNUR are subject to the TSCA section 13 import certification requirements which are codified at 19 CFR 12.118 through 12.127 and 127.28 and must certify that they are in compliance with the SNUR requirements. The EPA policy in support of the import certification appears at 40 CFR part 707.

IV. Substances Subject to this Rule

EPA is establishing significant new use and recordkeeping requirements for the following chemical substances under 40 CFR part 721 subpart E. In this unit, EPA provides a brief description for each substance, including its PMN number, chemical name (generic name if the specific name is claimed as CBI), CAS number (if applicable), basis for the action taken by EPA in the section 5(e) consent order for the substance (including the statutory citation and specific finding), and the CFR citation assigned in the regulatory text section of this rule. The specific uses which are designated as significant new uses are cited in the regulatory text section of the rule by reference to 40 CFR part 721 subpart B where the significant new uses are described in detail. Where the underlying section 5(e) order prohibits the PMN submitter from exceeding a specified production limit without performing specific tests to determine the health or environmental effects of a substance, the tests are described in this Unit. As explained further in Unit VI, the SNUR for such substances contains the same production limit, and exceeding the production limit is defined as a significant new use. Persons who intend to exceed the production limit must notify the Agency by submitting a significant new use notice at least 90 days in advance. In addition, this unit describes tests that are recommended by EPA to provide sufficient information to evaluate the substance, but for which no production limit has been established in the section 5(e) order. Descriptions of recommended tests are provided for informational purposes.

Each of these SNURs regulates a chemical substance subject to a section 5(e) order where the finding under TSCA is based solely on substantial production volume and substantial human or environmental exposure. In each of these cases, there was limited or no toxicity data available for the PMN substance, a potentially substantial production volume, and a potentially substantial human or environmental exposure. In such cases, EPA regulates new chemicals under section 5(e) by requiring certain toxicity tests. For instance chemicals with potentially substantial releases to surface waters would be subject to toxicity testing of aquatic organisms and chemicals with potentially substantial human exposures would be subject to health effects testing for mutagenicity, acute effects, and subchronic effects.

Each of these SNURs involves information which has been claimed as CBI. When a generic chemical name appears in this Unit, the specific name is claimed as CBI. In addition, each of the SNURs identified in this Unit involves a production limit as a significant new use. Because the production volume limit is contained in the section 5(e) order and has been claimed as CBI, the regulatory text incorporates the production volume by reference to the section 5(e) order. The procedures for determining whether a specific substance and/or a specific significant new use which are CBI are covered by a specific SNUR are described in Unit VII.

PMN Number P-89-448

Chemical name: (generic) Alkanepolyol phosphate ester.
CAS number: Not applicable.
Effective date of section 5(e) consent order: October 12, 1989.
Basis for section 5(e) order: The Order was issued under section 5(e)(1)(A)(i) and (ii)(II) of TSCA based on a finding that this substance is expected to be produced in substantial quantities and there may be significant or substantial human exposure.
Recommended testing: EPA has determined that the results of a mouse micronucleus assay (40 CFR 798.5395) and a 28-day repeated dose oral study in rats (OECD Guideline No. 407), with the following modifications: (a) for all test doses, a neurotoxicity functional observational battery (40 CFR 798.6050), and (b) for the highest test dose group only, histopathologic examination extended to include the testes/ovaries and lungs, plus neuropathology (40 CFR 798.6400) would help characterize possible effects of the substance. The PMN submitter has agreed not to exceed the production volume limit without performing these tests.
CFR citation: 40 CFR 721.288.

PMN Number P-89-650

Chemical name: (generic) Substituted ethylene diamine, methyl sulfate quaternized.
CAS number: Not applicable.
Effective date of section 5(e) consent order: October 23, 1989.
Basis for section 5(e) order: The Order was issued under section 5(e)(1)(A)(i) and (ii)(II) of TSCA based on a finding that this substance is expected to be produced in substantial quantities and there may be substantial environmental releases and significant or substantial human exposure.
Recommended testing: EPA has determined that the results of an acute algal study (40 CFR 797.1050), acute daphnid study (40 CFR 797.1300), and acute fish study (40 CFR 797.1400) would help characterize possible effects of the substance. The PMN submitter has agreed not to exceed the production volume limit without performing these tests.
CFR citation: 40 CFR 721.1062.

PMN Number P-89-653

Chemical name: (generic) Adipic acid, polymer with 1,4-cyclohexanedimethanol, dipropylene glycol, alkanepolyol, substituted alkanolamines, and carbomonocyclic dicarboxylic acid.
CAS number: Not applicable.
Effective date of section 5(e) consent order: October 31, 1989.
Basis for section 5(e) order: The Order was issued under section 5(e)(1)(A)(i) and (ii)(II) of TSCA based on a finding that this substance is expected to be produced in substantial quantities and there may be significant or substantial human exposure.
Recommended testing: EPA has determined that the results of 28-day oral (OECD 407), acute oral (40 CFR 798.1175), Ames assay (40 CFR 798.5265), and mouse micronucleus (40 CFR 798.5395) studies would help characterize possible effects of the substance. The PMN submitter has

agreed not to exceed the production volume limit without performing these tests.
CFR citation: 40 CFR 721.266.

PMN Numbers P-89-703, P-89-755, and P-89-756

Chemical name: (generic) Reaction products of secondary alkyl amines with a substituted benzenesulfonic acid and sulfuric acid.
CAS numbers: Not applicable.
Effective date of section 5(e) consent order: October 12, 1989.
Basis for section 5(e) order: The Order was issued under section 5(e)(1)(A)(i) and (ii)(II) of TSCA based on a finding that each of these substances is expected to be produced in substantial quantities and there may be significant or substantial human exposure.
Recommended testing: EPA has determined that the results of a 28-day repeated dose oral study in rats (OECD Guideline No. 407), with the following modifications: (a) for all test doses, a neurotoxicity functional observational battery (40 CFR 798.6050), and (b) for the highest test dose group only, histopathologic examination extended to include the testes/ovaries and lungs, plus neuropathology (40 CFR 798.6400), and a one-species oral developmental toxicity test (40 CFR 798.4900) for each of these three substances would help characterize their possible effects. The PMN submitter has agreed not to exceed the production volume limits without performing these tests.
CFR citation: 40 CFR 721.295.

V. Direct Final Rule Procedure

EPA is issuing today's SNURs as direct final rules, as described in 40 CFR 721.160(c)(3) and 721.170(d)(4). This approach reduces the time, relative to notice and comment rulemaking, during which a person may legally engage in a significant new use before the SNUR effective date and also conserves EPA resources while providing an adequate opportunity for public comment. For further information on this procedure, refer to the preamble to EPA's final rule amending part 721 (54 FR 31298, July 27, 1989).

Direct final SNURS will go into effect 60 days after the date of publication in the **Federal Register**, unless EPA receives a written notice within 30 days after the date of publication that someone wishes to make adverse or critical comments on a specific SNUR. If EPA receives such a notice, EPA will issue a notice to withdraw the direct final SNUR(s) for the specific substance(s) to which the adverse or critical comments apply. Any person who submits a notice of intent to submit adverse or critical comments must identify the substance and the new use to which it applies. EPA will not withdraw a SNUR for a substance not identified in a notice. If EPA receives such a notice, EPA will then propose a SNUR for the specific substance(s) with a 30-day comment period.

VI. Test Data and Other Information

EPA recognizes that section 5 of TSCA does not require persons to develop any particular test data before submitting a SNUR notice. Persons are only required to submit test data in their possession or control and to describe any other data known to or reasonably ascertainable by them. However, EPA suggests potential SNUR notice submitters consider conducting tests that would permit a reasoned evaluation of the potential risks posed by a particular substance when utilized for an intended use.

EPA has established production limits in the section 5(e) consent orders for the substances that are subject to this rule. Under the consent orders, the production limit cannot be exceeded unless the PMN submitters first submit the results of tests that would permit a reasoned evaluation of the potential risks posed by these substances. Each such order contains detailed procedures for dealing with situations where the resulting data are invalid or equivocal, or show that the substance will present an unreasonable risk of injury under the exposure limitations in the order. SNURs contain the same production limits as the consent orders; exceeding these production limits is defined as a significant new use.

Although SNURs in today's rule contain the same production limits established in the section 5(e) consent orders, the rule does not set out requirements for specific tests or protocols. A listing of the tests specified in the section 5(e) order for each substance subject to today's rule is included in Unit IV. The studies specified in the section 5(e) order may not be the only means of addressing the potential risks of the substance. However, SNUR notices submitted for significant new uses without any test data may increase the likelihood that EPA will take action under section 5(e), particularly if satisfactory test results have not been obtained from a prior submitter.

EPA believes it is likely that in most cases the PMN submitter will conduct the tests identified in the section 5(e) order. Accordingly, before beginning to conduct a study, a person subject to the SNUR should contact EPA to determine whether the study has already been produced. EPA encourages persons to consult with EPA before selecting a protocol for testing a substance. As part of this pre-notice consultation, EPA will discuss the test data it believes necessary to evaluate a significant new use of the substance. Test data should be developed according to TSCA good laboratory practice standards at 40 CFR part 792. Failure to do so may lead EPA to find such data to be insufficient to evaluate reasonably the health or environmental effects of the substance.

SNUR notice submitters should be aware that EPA will be better able to evaluate SNUR notices which provide detailed information on: (1) Human exposure and environmental release that may result from the significant new use of the chemical substances; (2) potential benefits of the substances; and (3) information on risks posed by the substances compared to risks posed by potential substitutes.

VII. Determining When a Substance or Use Is Designated in the Rule

In some instances, EPA establishes a significant new use set at production volumes which have been claimed as CBI. Other information, including the specific chemical name of the substance, may also be claimed CBI. EPA has decided it is appropriate to keep this information confidential to protect the interest of the original PMN submitters.

EPA will reveal whether a specific chemical substance is subject to one of these SNURs only to a manufacturer or importer who has shown a *bona fide* intent to manufacture or import the substance. To establish a *bona fide* intent, the person must submit the information required under 40 CFR 721.11(b). EPA will make a determination as to whether the person has established a *bona fide* intent to manufacture or import the substance. If the person has established a *bona fide* intent, EPA will inform the person whether the chemical substance is included in the TSCA Inventory and subject to a specific SNUR.

Each of these SNURs designates exceeding a specific aggregate production volume as the significant new use by reference to 40 CFR 721.80(q). Section 721.80(q) is used when the specific volume is identified in the section 5(e) consent order but has been claimed as CBI. EPA promulgated a procedure to deal with the situation where a specific significant new use is CBI. This procedure appears in 40 CFR 721.575(b)(1) and is similar to that in § 721.11 for situations where the chemical identity of the substance

subject to a SNUR is CBI. This procedure is incorporated by reference into each of these SNURs.

Under the procedure incorporated from § 721.575(b)(1), a manufacturer or importer (processors are not affected by the production volume significant new use unless they are also manufacturing or importing the substance) must show that it has a *bona fide* intent to manufacture or import the substance and must identify the specific use for which it intends to manufacture or import the substance. In the case of these SNURs, the use would be the specific aggregate manufacturing and import volume intended by the person. If EPA concludes that the person has shown a *bona fide* intent to manufacture or import the substance, EPA will tell the person whether the production volume identified in the *bona fide* submission would be a significant new use under the rule. Since the chemical identities of the substances subject to these SNURs are also CBI, manufacturers and processors can combine the *bona fide* submission under the procedure in § 721.575(b)(1) with that under § 721.11 into a single step.

If a manufacturer or importer is told that the production volume identified in the *bona fide* submission would not be a significant new use, i.e. it is below the level that would be a significant new use, that person can manufacturer or import the substance as long as the aggregate amount does not exceed that identified in the *bona fide* submission to EPA. If the person later intends to exceed that volume, a new *bona fide* submission would be necessary to determine whether that higher volume would be a significant new use. EPA is considering whether to adopt a special procedure for use when CBI production are designated as significant new uses. Under that procedure, if a person showed a *bona fide* intent to manufacture or import the substance, under the procedure described in § 721.11, the person would automatically be told any production volume that would be a significant new use. Thus the person would not have to make multiple *bona fide* submissions to EPA for the same substance to remain in compliance with the SNUR, as could be the case under the procedures in § 721.575(b)(1).

VIII. Applicability of Rule to Uses Occurring Before Effective Date of the Final Rule

To establish a significant new use, EPA must determine that the use is not ongoing. The chemical substances subject to this rule have recently undergone premanufacture review. In those cases where a section 5(e) order has been issued, the notice submitter is prohibited by the section 5(e) order from undertaking activities which EPA is designating as a significant new use. If a Notice of Commencement of Manufacture (NOC) has not yet been submitted to EPA for the substance and the substance has not yet been added to the TSCA Chemical Inventory, no other person may commence such activities without first submitting a PMN to EPA. Therefore, EPA has concluded that in cases where EPA has not received a NOC, the uses designated in the SNUR are not ongoing. Those who submitted the PMNs covered by this rule have not submitted NOCs for these substances.

However, EPA recognizes that if a substance identified in a SNUR is added to the Inventory prior to the effective date of the rule, the substance may be manufactured, imported, or processed by other persons for a significant new use as defined in this rule before the effective date of the rule.

EPA has decided that the intent of section 5(a)(1)(B) is best served by designating a use as a significant new use as of the date of publication rather than as of the effective date of the rule. If the uses which had commenced between the date of publication and the effective date were considered ongoing, rather than new, any person could defeat the SNUR by initiating a significant new use before the effective date. This would make it difficult for EPA to establish SNUR notice requirements.

Thus, persons who begin commercial manufacture, import, or processing of the substances regulated through this SNUR will have to cease any such activity before the effective date of this rule. To resume their activities, these persons would have to comply with all applicable SNUR notice requirements and wait until the notice review period, including all extensions, expires.

EPA has promulgated provisions to allow such persons to comply with this SNUR before the effective date. If a person were to meet the conditions of advance compliance in 40 CFR 721.45(h), the person will be considered to have met the requirements of the final SNUR for those activities. If persons who begin commercial manufacture, import, or processing of the substance between publication and the effective date of the SNUR do not meet the conditions of advance compliance, they must cease that activity before the effective date of the rule. To resume their activities, these persons would have to comply with all applicable SNUR notice requirements and wait until the notice review period, including all extensions, expires.

IX. Economic Analysis

EPA has evaluated the potential costs of establishing significant new use notice requirements for potential manufacturers, importers, and processors of the chemical substances subject to this rule. EPA's complete economic analysis is available in the public record for this rule.

X. Rulemaking Record

EPA has established a record for this rulemaking (docket control number OPTS–50575). The record includes information considered by EPA in developing this rule.

A public version of this record containing nonconfidential materials is available for reviewing and copying from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays, in the TSCA Public Docket Office, located at Rm. NE–G004, 401 M St., SW., Washington, DC.

Any person who submits comments claimed as CBI must mark the comments as "confidential," "trade secret," or other appropriate designation. Comments not claimed as confidential at the time of submission will be placed in the public file. Any comments marked as confidential will be treated in accordance with the procedures in 40 CFR part 2. Any person submitting comments claimed to be confidential must prepare and submit a public version of the comments that EPA can place in the public file.

XI. Regulatory Assessment Requirements

A. Executive Order 12291

Under Executive Order 12291, EPA must judge whether a rule is "major" and therefore requires a Regulatory Impact Analysis. EPA has determined that this rule will not be a "major" rule because it will not have an effect on the economy of $100 million or more, and it will not have a significant effect on competition, costs, or prices. While there is no precise way to calculate the total annual cost of compliance with this rule, EPA estimates that the cost for submitting a significant new use notice would be approximately $4,500 to $11,000, including a $2,500 user fee payable to EPA to offset EPA costs in processing the notice. EPA believes that, because of the nature of the rule and the substances involved, there will be few SNUR notices submitted. Furthermore, while the expense of a notice and the uncertainty of possible EPA regulation may discourage certain innovation, that impact will be limited because such

factors are unlikely to discourage an innovation that has high potential value.

This regulation was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (5 U.S.C. 605(b)), EPA has determined that this rule will not have a significant impact on a substantial number of small businesses. EPA has not determined whether parties affected by this rule will likely be small businesses. However, EPA expects to receive few SNUR notices for the substances. Therefore, EPA believes that the number of small businesses affected by this rule will not be substantial, even if all of the SNUR notice submitters were small firms.

C. Paperwork Reduction Act

The information collection requirements contained in this rule have been approved by OMB under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), and have been assigned OMB control number 2070–0012.

Public reporting burden for this collection of information is estimated to vary from 30 to 170 hours per response, with an average of 100 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM–223, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; and to Office of Management and Budget, Paperwork Reduction Project (2070–0012), Washington, DC 20503.

List of Subjects in 40 CFR Part 721

Chemicals, Environmental protection, Hazardous materials, Recordkeeping and reporting requirements, Significant new uses.

Dated: April 13, 1990.

Victor J. Kimm,

Acting Assistant Administrator for Pesticides and Toxic Substances.

Therefore, 40 CFR part 721 is amended as follows:

PART 721—[AMENDED]

1. The authority citation for part 721 continues to read as follows:

Authority: 15 U.S.C. 2604 and 2607.

2. By adding new § 721.266 to subpart E to read as follows:

§ 721.266 Adipic acid, polymer with 1,4-cyclohexane-dimethanol, dipropylene glycol, alkanepolyol, substituted alkanolamines, and carbomonocyclic dicarboxylic acid (generic name).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as adipic acid, polymer with 1,4 - cyclohexanedimethanol, dipropylene glycol, alkanepolyol, substituted alkanolamines, and carbomonocyclic dicarboxylic acid (PMN P–89–653) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Uses as specified in § 721.80(q).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* The following recordkeeping requirements are applicable to manufacturers, importers, and processors of this substance: recordkeeping requirements specified in § 721.125(a), (b), (c), and (i).

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.575(b)(1) apply to this section.

(Approved by the Office of Management and Budget under OMB control number 2070–0012)

3. By adding new § 721.288 to subpart E to read as follows:

§ 721.288 Alkanepolyol phosphate ester (generic name).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as alkanepolyol phosphate ester (P–89–448) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Uses as specified in § 721.80(q).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* The following recordkeeping requirements are applicable to manufacturers, importers, and processors of this substance: Recordkeeping requirements specified in § 721.125(a), (b), (c), and (i).

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.575(b)(1) apply to this section.

(Approved by the Office of Management and Budget under OMB control number 2070–0012)

4. By adding new § 721.295 to subpart E to read as follows:

§ 721.295 Reaction products of secondary alkyl amines with a substituted benzenesulfonic acid and sulfuric acid (generic name).

(a) *Chemical substances and significant new uses subject to reporting.* (1) The chemical substances identified generically as reaction products of secondary alkyl amines with a substituted benzenesulfonic acid and sulfuric acid (PMNs P–89–703, P–89–755, and P–89–756) are subject to reporting under this section for significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Uses as specified in § 721.80(q).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* The following recordkeeping requirements are applicable to manufacturers, importers, and processors of these substances: Recordkeeping requirements specified in § 721.125(a), (b), (c), and (i).

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.575(b)(1) apply to this section.

(Approved by the Office of Management and Budget under OMB control number 2070–0012)

5. By adding new § 721.1082 to subpart E to read as follows:

§ 721.1082 Substituted ethylene diamine, methyl sulfate quaternized (generic name).

(a) *Chemical substance and significant new uses subject to*

reporting. (1) The chemical substance identified generically as ethylene diamine, methyl sulfate quaternized (P–89–650) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Uses as specified in § 721.80(q).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* The following recordkeeping requirements are applicable to manufacturers, importers, and processors of this substance: Recordkeeping requirements specified in § 721.125(a), (b), (c), and (i).

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.575(b)(1) apply to this section.

(Approved by the Office of Management and Budget under OMB control number 2070–0012)

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